

## WHAT IS CLAIMED IS

1. Use of recombinant HSA in dialysis, wherein the recombinant HSA has been purified from accompanying fatty acids during its production.
- 5 2. The use according to claim 1, wherein the recombinant HSA is further purified from other accompanying substances, preferably proteins or metal ions.
- 10 3. The use according to claims 1 or 2, wherein the recombinant HSA is obtained from a transgenic non-human animal or from a transgenic plant.
4. The use according to claim 3, wherein HSA is obtained from a bovine, ovine, porcine, equine, rodent or caprine source.
- 15 5. The use according to claim 4, wherein HSA is obtained from the milk or blood of the transgenic non-human animal.
6. The use according to claim 5, wherein HSA is obtained from the milk of a lactating bovine.
- 20 7. The use according to claim 3, wherein HSA is obtained from an egg of a transgenic bird.
- 25 8. The use according to claim 1, wherein the recombinant HSA is purified from accompanying fatty acids by the use of activated charcoal.

9. The use according to claim 8, wherein the preparation of recombinant HSA comprises a clarification step.
- 5 10. The use according to claim 9, wherein the clarification is performed by filtration.
- 10 11. The use according to claim 1, wherein the preparation of recombinant HSA comprises the precipitation of the recombinant HSA from a solution containing recombinant HSA.
12. The use according to claim 11, wherein the preparation of recombinant HSA comprises the precipitation of contaminating proteins from a solution containing recombinant HSA.
- 15 13. The use according to claim 1, wherein the preparation of recombinant HSA comprises a chromatography purification step.
14. The use according to claim 13, wherein the chromatography step involves an affinity- or ion exchange chromatography step.
- 20 15. The use according to claim 1, wherein the recombinant HSA is present in the dialysate liquid.
- 25 16. The use according to claim 15, wherein HSA is present in the dialysate liquid in a concentration in the range of about 1 about 40% by weight of the composition.

17. The use according to claim 16, wherein the range is of about 5 to about 30% by weight of the composition.
18. The use according to claim 1, wherein the recombinant HSA is present on a dialysate membrane.
19. A dialysate liquid containing recombinant HSA, wherein the recombinant HSA has been purified from accompanying fatty acids during its production.
20. The dialysate liquid according to claim 19, wherein the recombinant HSA is further purified from other accompanying substances, preferably proteins or metal ions.
21. The dialysate liquid according to claims 19 or 20 that is bicarbonate buffered comprising in form of ions sodium from about 130 to about 145 mmol/1000 ml, calcium from about 1.0 to about 2.5 mmol/1000 ml, potassium from about 2.0 to about 4.0 mmol/1000 ml, magnesium from about 0.2 to about 0.8 mmol/1000 ml, chloride from about 100 to about 110 mmol/1000 ml, bicarbonate from about 30 to about 40 mmol/1000 ml, acetate from about 2 to about 10 mmol/1000 ml, and human serum albumin from about 1 to about 50 g/100 ml.
22. The dialysate liquid according to claims 19 or 20 that is bicarbonate buffered comprising in form of ions sodium from about 130 to about 145 mmol/1000 ml, calcium from about 1.0 to about 2.5 mmol/1000 ml, potassium from about 2.0 to about 4.0 mmol/1000 ml, magnesium from about 0.2 to about 0.8 mmol/1000 ml, chloride from about 100 to about 110 mmol/1000 ml, bicarbonate from about 30 to about 40 mmol/1000 ml, acetate from about 2 to

about 10 mmol/1000 ml, and human serum albumin from about 6 to about 40 g/100 ml.

23. The dialysate liquid according to claims 19 or 20 that is bicarbonate buffered comprising in form of ions sodium from about 130 to about 145 mmol/1000 ml, calcium from about 1.0 to about 2.5 mmol/1000 ml, potassium from about 2.0 to about 4.0 mmol/1000 ml, magnesium from about 0.2 to about 0.8 mmol/1000 ml, chloride from about 100 to about 110 mmol/1000 ml, bicarbonate from about 30 to about 40 mmol/1000 ml, acetate from about 2 to about 10 mmol/1000 ml, and human serum albumin from about 8 to about 30 g/100 ml.
24. The dialysate liquid according to claims 19 or 20 that is bicarbonate buffered comprising in form of ions sodium from about 130 to about 145 mmol/1000 ml, calcium from about 1.0 to about 2.5 mmol/1000 ml, potassium from about 2.0 to about 4.0 mmol/1000 ml, magnesium from about 0.2 to about 0.8 mmol/1000 ml, chloride from about 100 to about 110 mmol/1000 ml, bicarbonate from about 30 to about 40 mmol/1000 ml, acetate from about 2 to about 10 mmol/1000 ml, and human serum albumin from about 8 to about 20 g/100 ml.
25. The dialysate liquid according to claims 19 or 20 that is acetate buffered comprising in form of ions sodium from about 130 to about 145 mmol/1000 ml, calcium from about 1.0 to about 2.5 mmol/1000 ml, potassium from about 2.0 to about 4.0 mmol/1000 ml, magnesium from about 0.2 to about 0.8 mmol/1000 ml, chloride from about 100 to about 110 mmol/1000 ml, acetate from about 30 to about 40 mmol/1000 ml, human serum albumin from about 1 to about 50 g/100 ml.

26. The dialysate liquid according to claims 19 or 20 that is acetate buffered comprising in form of ions sodium from about 130 to about 145 mmol/1000 ml, calcium from about 1.0 to about 2.5 mmol/1000 ml, potassium from about 2.0 to about 4.0 mmol/1000 ml, magnesium from about 0.2 to about 0.8 mmol/1000 ml, chloride from about 100 to about 110 mmol/1000 ml, acetate from about 30 to about 40 mmol/1000 ml, human serum albumin from about 6 to about 40 g/100 ml.
27. The dialysate liquid according to claims 19 or 20 that is acetate buffered comprising in form of ions sodium from about 130 to about 145 mmol/1000 ml, calcium from about 1.0 to about 2.5 mmol/1000 ml, potassium from about 2.0 to about 4.0 mmol/1000 ml, magnesium from about 0.2 to about 0.8 mmol/1000 ml, chloride from about 100 to about 110 mmol/1000 ml, acetate from about 30 to about 40 mmol/1000 ml, human serum albumin from about 8 to about 30 g/100 ml.
28. The dialysate liquid according to claims 19 or 20 that is acetate buffered comprising in form of ions sodium from about 130 to about 145 mmol/1000 ml, calcium from about 1.0 to about 2.5 mmol/1000 ml, potassium from about 2.0 to about 4.0 mmol/1000 ml, magnesium from about 0.2 to about 0.8 mmol/1000 ml, chloride from about 100 to about 110 mmol/1000 ml, acetate from about 30 to about 40 mmol/1000 ml, human serum albumin from about 8 to about 20 g/100 ml.
29. A membrane for the separation of protein-bound substances from a protein-containing liquid (A) containing these substances by dialysis against a dialysate liquid (B) wherein recombinant HSA which has been purified from

accompanying fatty acids during its production is attached to at least one side of the membrane and the membrane has such a pore size that the protein-bound substances can pass through the membrane.

- 5     30.     The membrane according to claim 29, wherein the recombinant HSA is further purified from other accompanying substances, preferably proteins or metal ions
- 10     31.     The membrane according to claims 29 or 30 comprising two functionally different parts (regions), one part having an actual separating membrane function permitting the protein-bound substances to pass through and excluding the protein(s) which had bound the protein-bound substances in liquid (A) and the recombinant HSA in liquid (B), and the other part having a port- and adsorption-function, and the membrane being coated on at least one  
15     side with a protein having an acceptor function for the protein-bound substances.
- 20     32.     The membrane according to claims 29 or 30 comprising one part having an actual separating membrane function with a tunnel-like structure on the liquid (A) side, the tunnels having a length less than about 10  $\mu\text{m}$  and having a diameter sufficiently small to exclude the protein in liquid (A) and the acceptor protein in liquid (B), and a part with a port-and adsorption-structure on the dialysate liquid (B) side.
- 25     33.     The membrane according to claim 32 wherein the length of the tunnels is less than about 5  $\mu\text{m}$ .

34. The membrane according to claim 32 wherein the length of the tunnels is less than about 0.1  $\mu\text{m}$ .
35. The membrane according to claims 29 or 30 wherein the membrane material is selected from the group consisting of polysulfones, polyamides, polycarbonates, polyesters, acrylonitrile polymers, vinyl alcohol polymers, acrylate polymers, methacrylate polymers, and cellulose acetate polymers.
36. The membrane according to claim 35 wherein the membrane material is a polysulfone.
37. A disposable set for the separation of protein-bound substances from plasma or blood containing these substances including a dialyzer comprising a membrane according to claims 29 or 30.
38. The disposable set according to claim 37 wherein the dialyzer contains on the dialysate liquid (B) side a human serum albumin containing liquid.
39. A disposable set for the separation of protein-bound substances from plasma or blood containing these substances including a dialyzer comprising a membrane according to claims 29 or 30, a second conventional dialyzer for hemodialysis, a conventional charcoal adsorber unit for hemoperfusion, and a conventional ion exchange resin unit for hemoperfusion interconnected by tubing and a unit of a recombinant human serum albumin containing dialysate liquid (B), wherein the recombinant HSA has been purified from accompanying fatty acids during its production.

40. A disposable set for the separation of protein-bound substances from plasma or blood containing said substances including a dialyzer comprising a membrane according to claims 29 or 30 and being filled on the dialysate liquid (B) side with a human serum albumin containing liquid, a second  
5 conventional dialyzer for hemodialysis, a conventional charcoal adsorber unit for hemoperfusion, and a conventional ion exchange resin unit for hemoperfusion interconnected by tubing and a unit of a human serum albumin containing dialysate liquid, wherein the recombinant HSA has been purified from accompanying fatty acids during its production.
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41. A method for the separation of protein-bound substances from a protein-containing liquid (A) containing these substances comprising dialyzing said liquid (A) against a dialysate liquid (B) by means of a membrane, said membrane permitting passage of the protein-bound substances to a dialysate  
15 liquid (B) site, and by means of recombinant HSA, said HSA being present either in free form in the dialysate liquid (B) and/or attached to at least one side of the membrane, and wherein the recombinant HSA has been purified from accompanying fatty acids during its production.
- 20 42. The method of claim 41, wherein the recombinant HSA is further purified from other accompanying substances, preferably proteins or metal ions.
43. A method for the separation of protein-bound substances from a protein  
25 containing liquid (A) containing these substances comprising dialyzing said liquid (A) against a dialysate liquid (B) containing recombinant HSA, wherein the recombinant HSA has been purified from accompanying fatty acids during its production and by means of a membrane comprising two functionally different parts, one part, having an actual separating membrane function



5 permitting passage of the protein-bound substances and the water-soluble substances and excluding the protein(s) which had bound the protein-bound substances in liquid (A) and the recombinant HSA in liquid (B), and the other part having a port- and adsorption-function, and the membrane being coated with the recombinant HSA.

44. The method of claim 43, wherein the recombinant HSA is further purified from other accompanying substances, preferably proteins or metal ions.
- 10 45. The method of claims 41 or 43, wherein the membrane comprises one part having an actual separating membrane function with a tunnel-like structure on the liquid (A) side, the tunnels having a length less than about 10  $\mu\text{m}$  and having a diameter sufficiently small to exclude the protein in liquid (A) and the recombinant HSA in liquid (B), and a part with a port- and adsorption-  
15 structure on the dialysate liquid (B) side.
46. The method of claim 45 wherein the length of the tunnels of the membrane is less than about 5  $\mu\text{m}$ .
- 20 47. The method of claim 46 wherein the length of the tunnels of the membrane is less than about 0.1  $\mu\text{m}$ .
48. The method of claims 41 or 43 wherein the membrane material is selected from the group consisting of polysulfones, polyamides, polycarbonates,  
25 polyesters, acrylonitrile polymers, vinyl alcohol polymers, acrylate polymers, methacrylate polymers, and cellulose acetate polymers.
49. The method of claim 48 wherein the membrane material is a polysulfone.

50. The method of claims 41 or 43 wherein the protein-containing liquid (A) is selected from the group consisting of plasma and blood.
- 5 51. The method of claims 41 or 43 wherein the membrane is coated with a solution comprising recombinant HSA, wherein the recombinant HSA has been purified from accompanying fatty acids during its production.
- 10 52. The method of claims 41 or 43 wherein the dialysate liquid (B) comprises recombinant human serum albumin in a concentration from about 1 to about 50 grams per 100 ml, preferably from about 6 to about 40 grams per 100 ml, more preferably from about 8 to about 30 grams per 100 ml, even more preferably in a concentration from about 8 to about 20 grams per 100 ml.
- 15 53. Use of recombinant human serum albumin (HSA) for the preparation of a pharmaceutical composition for the treatment of liver failure, wherein the recombinant HSA has been purified from fatty acids during production.